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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY-DOCKET NO.
09/238,972	01/27/99	MACLEOD	DS-232-LTP-3

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HM22/0813

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ART UNIT	PAPER NUMBER
1635	7

08/13/99

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/238,972Applicant(s)
MacLeodExaminer
Andrew WangGroup Art Unit
1635☒ Responsive to communication(s) filed on Jun 1, 1999☒ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-20 is/are pending in the application.Of the above, claim(s) 10-15 and 18-20 is/are withdrawn from consideration.☐ Claim(s) _____ is/are allowed.☒ Claim(s) 1-9, 16, and 17 is/are rejected.☐ Claim(s) _____ is/are objected to.☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been☐ received.☐ received in Application No. (Series Code/Serial Number) _____.☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Applicant's election with traverse of group I, claims 1-9, 16, and 17 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that a single inventive concept is intertwined between groups I, II, and III and that would not be an undue burden to examine all three groups. This is not found persuasive because applicants argue the invention on PCT guidelines regarding a single inventive concept. It should be noted that the instant application was not filed under 35 U.S.C. 371 for national stage applications and therefore not subject to unity of invention guidelines. Moreover, as noted in the restriction requirement mailed April 13, 1999, the three groups of invention are unrelated and have unrelated modes of operation as well as being materially different.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 10-15 and 18-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected group, the requirement having been traversed in Paper No. 6.

3. Applicants arguments concerning C-I-P priority to application serial number 08/187,634 ('634), U.S. Patent 5,866,123, were not found persuasive. Applicants allege that '634 makes reference to Maniatis et al., that teaches general molecular techniques including antisense

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technology, and therefore provides sufficient support for the instantly claimed antisense oligos to receive priority benefit of '634 as well as 07/686,322 and 07/509,684. It should be noted that a mere statement incorporating a reference is not sufficient for support of a claimed invention, in this case, antisense technology. To properly incorporate a reference, applicants must specifically cite which pages or passages are being incorporated by reference. Since applicants do not specifically cite the pertinent pages of Maniatis et al. that discusses antisense technology in the specification of '634, applicants are not entitled to priority benefit of '634 nor the earlier filed applications '322 or '684. Therefore, priority of the instant application remains January 27, 1999, the filing date of the instant application.

4. Claims 3, 16, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,312,733 (MacLeod) for the same reasons of record as set forth in the Office action mailed April 13, 1999, Paper No. 4.

Applicants arguments were not found persuasive since applicants only argue the alleged priority date which has been addressed above.

5. Claims 3 and 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession

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of the claimed invention for the same reasons of record as set forth in the Office action mailed April 13, 1999, Paper No. 4.

Applicant's arguments filed June 1, 1999 have been fully considered but they are not persuasive. From the outset, applicants correctly note that neither claim 2 nor 16 is drawn to a pharmaceutical composition and further state that claim 3 is the only claim drawn to a pharmaceutical composition. The transposition of claims 2 and 3 in the rejection of record was due to a typographical error. The actual rejection that was intended to include claims 3 and 16 not 2 and 16 which has been noted by applicants in their statement regarding the absence of "pharmaceutical" in claims 2 and 16. Therefore, claims 3 and 16 are rejected under 35 U.S.C. 112, first paragraph. The examiner sincerely apologizes for any inconvenience this may have caused the applicants.

Nevertheless, applicants allege that although primary structure is not the sole determinant of antisense function, it is the major determinant and since applicants have shown one antisense oligo that was inhibitory, other inhibitory oligos could be found and therefore, applicants were indeed in possession of the claimed invention. Although it is not disputed that there is a possibility of finding other inhibitory oligos, applicants have not provided any description, ie. nucleotide sequences, of these supposed oligos. Moreover, applicants have not provided any evidence to particular regions that were shown to be susceptible to antisense inhibition and therefore have not provided a sufficient description of the claimed genus of antisense oligos.

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As for the pharmaceutical compositions, applicants allege that the specification discloses using liposomes and various viral vectors as possible carriers. The simple disclosure of these possible carriers is not sufficient to describe a pharmaceutical composition since a pharmaceutical composition would indicate that the composition would have some type of ameliorative effect on a disease condition, which applicants have not demonstrated.

6. Claims 1-9 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification is only enabling for claims limited to an antisense oligo consisting of SEQ ID NO:2 and a method of inhibiting CAT2 expression using said antisense oligo. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for the same reasons of record as set forth in the Office action mailed April 13, 1999, Paper No. 4.

Applicant's arguments filed June 1, 1999 have been fully considered but they are not persuasive. Applicants allege that the claimed disease conditions claimed are all characterized by undesirable levels of nitric oxide and that the inhibition of CAT2 would lead to a decrease in the level of nitric oxide, therefore, proving to be effective in treating said disease condition but as noted, the written description rejection, applicants were not in possession of said oligos. Moreover, simply noting that the claimed diseases are associated with aberrant nitric oxide expression does not provide evidence that the inhibition of CAT2 with antisense oligos would lead to an ameliorative effect. Additionally, applicants merely speculate that an antisense

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approach is a viable approach to CAT2 regulation and that the doubts about antisense therapy as expressed by Rojanasakul and Branch will not be necessarily true for the instant invention without providing any evidence supporting the alleged enablement of the claimed invention.

Further, applicants note that 55% of Hokes oligos were successful enough to include in the patent and therefore provides a reasonable level of success for enabling the claimed invention, but applicants arguments concerning Hokes level of enablement is irrelevant since each application is based on its own merits and the transcript which Hoke targeted is an entirely different gene.

Lastly, applicants allege that the Gewirtz and Branch references is contrary to what Hoke discloses since Hoke had a 55% success rate for his oligos but contrary to applicants assertions, Hoke supports the unpredictability of antisense oligos by disclosing the divergent activity of oligos targeting the same region.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew Wang whose telephone number is (703) 306-3217. The examiner can normally be reached on Monday to Thursday from 7:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached on (703) 308-4003. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Andrew Wang
August 9, 1999

DAVID GUZO
PRIMARY EXAMINER
